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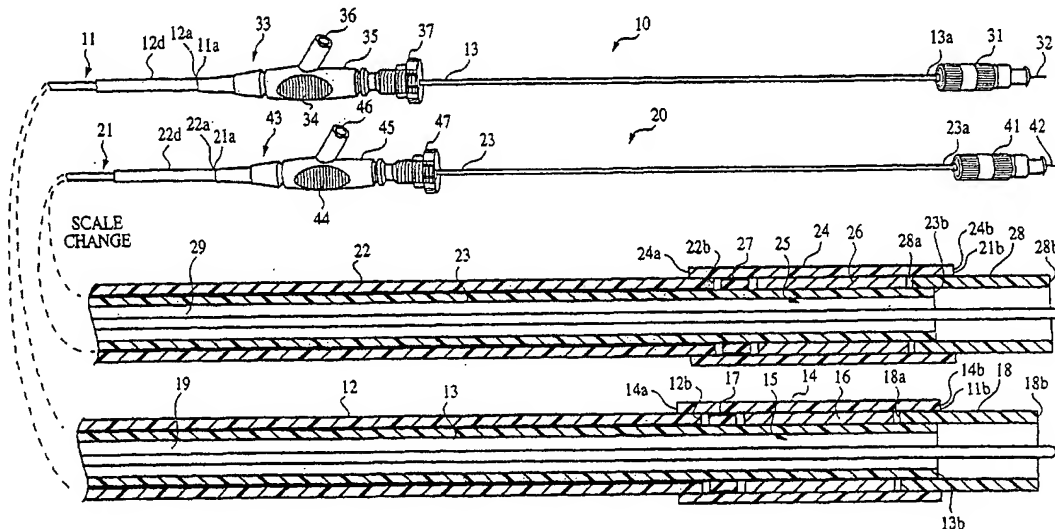
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(54) Title: **BILIARY STENT INTRODUCER SYSTEM**



(57) Abstract: A stent delivery system and method for positioning a first and second stent in the main lumen and the first and second branch lumens of a bifurcation. The stent delivery system comprises two delivery catheters (10, 20) slidably disposed within the lumen of an endoscope (8).

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"BILIARY STENT INTRODUCER SYSTEM"

BACKGROUND

[0001] The invention generally relates to stent devices for maintaining the patency of the biliary tree, or common bile duct and methods for introducing stent devices. Figure 1 is a partial, cross-sectional view of a biliary system 2 showing the common bile duct 2a, the left hepatic duct 2b, the right hepatic duct 2c, the gall bladder 2d, the pancreas 2e and the duodenum 2f.

[0002] Strictures or occlusions that develop in the upper common bile duct and/or the left and right hepatic ducts can interfere with the proper drainage of those ducts. Figure 2 shows a partial, cross-sectional view of the biliary system 2 of Figure 1 showing strictures 3 within the common bile duct 2a, the left hepatic duct 2b and the right hepatic duct 2c. A successful method of treatment to reestablish proper drainage through the diseased ducts has been to open the ducts by placing prostheses, such as self-expanding biliary stents, within the restrictions. Because of the branched configuration of the duct anatomy it is often necessary to place two or more stents in an overlying or side-by-side configuration. However, currently available stent and introducer geometries are such that placement of a first stent may interfere with the placement of a second stent. Figure 3 illustrates the problem associated with the prior art method of placing stents in the common bile duct 2a and the left and right hepatic ducts 2b, 2c, *i.e.* the placement of a first stent 16 within the common bile duct 2a and the left hepatic duct 2b that obscures the access to the stricture in the right hepatic duct 2c.

[0003] Consequently, there is a need for a self-expanding stent delivery system which overcomes the problems associated with prior art delivery systems. Specifically, there is a need for a self-expanding stent delivery system which allows the physician to simultaneously place a first and second stent in the side branches and main lumen of a bifurcation.

first stent retaining area such that the first stent proximal end abuts the first pusher band, and a first wire guide lumen extending proximally from the first introducer distal end through at least a portion of the first introducer. The first outer catheter includes a first proximal outer catheter having a first proximal outer diameter and a first distal outer catheter having a first distal outer diameter.

[0007] The second introducer comprises a second outer catheter, a second inner shaft located coaxially within the second outer catheter, a stent retaining area located on a distal portion of the second inner shaft, a second stent tip attached to a distal end of the second inner shaft, a second pusher band located proximate the second stent retaining area, a second stent mounted on the second stent retaining area such that the second stent proximal end abuts the second pusher band, and a second wire guide lumen extending proximally from the second introducer distal end through at least a portion of the second introducer. The second outer catheter includes a second proximal outer catheter having a second proximal outer diameter and a second distal outer catheter having a second distal outer diameter.

[0008] The stent delivery system of the present invention may be configured such that the sum of the first proximal outer diameter and the second distal outer diameter is less than the inner diameter of the working channel of the endoscope. Alternatively, the stent delivery system of the present invention may be configured such that the sum of the first proximal outer diameter, the second distal outer diameter and at least one of a first and second wire guide diameters is less than the inner diameter of the working channel of the endoscope. As another alternative, the stent delivery system may be configured such that the first proximal outer diameter is disposed adjacent to the second distal outer diameter while inside the working channel of the endoscope.

[0009] In a fourth aspect of the invention, the method of placing a first stent within a first branch lumen and a main lumen of a bifurcation and placing a second stent within a second branch lumen and the main lumen of the bifurcation comprises the steps of: providing an endoscope having a first introducer with the first stent retained on a first distal portion and a second introducer having the second stent retained on a second distal portion disposed in an adjacent

[0013] Figure 3 is a partial, cross-sectional view of the biliary system of Figure 2 illustrating a stent that has been placed in the common bile duct and the left hepatic duct.

[0014] Figure 4 is a partial, cross-sectional view of the biliary system of Figure 2 illustrating the placement of first and second stents in the left and right hepatic ducts, respectively, and the common bile duct according to a preferred method of the present invention.

[0015] Figure 5 is a cross-sectional view of a preferred embodiment of the first and second introducers of the stent delivery system of the present invention.

[0016] Figure 6 is a partial, cross-sectional view of a distal portion of the first introducer of Figure 5.

[0017] Figure 6A is a partial, cross-sectional view of a distal portion of the second introducer of Figure 5.

[0018] Figure 7 is a partial, cross-sectional view of an alternate preferred embodiment of the distal portion of the first introducer of Figure 5.

[0019] Figure 7A is a partial, cross-sectional view of an alternate preferred embodiment of the distal portion of the first introducer of Figure 5.

[0020] Figure 8 is a partial, cross-sectional view of the distal portion of the first introducer of Figure 5 showing the wire guide and wire guide lumen.

[0021] Figure 8A is a partial, cross-sectional view of the distal portion of the second introducer of Figure 5 showing the wire guide and wire guide lumen.

[0022] Figure 9 is a partial, cross-sectional view of the distal portion of the first introducer of Figure 5 showing an alternate embodiment of the wire guide and the wire guide lumen.

[0023] Figure 9A is a partial, cross-sectional view of the distal portion of the second introducer of Figure 5 showing an alternate embodiment of the wire guide and the wire guide lumen.

[0024] Figure 10 is a partial, cross-sectional view of the distal portion of the first introducer of Figure 5 showing an alternate embodiment of the wire guide and the wire guide lumen.

are similar with respect to the views shown in Figures 5-13. Therefore, reference will be made to both first and second introducers 10, 20 in the description below.

[0031] As shown in Figure 5, introducer 10, 20 has a proximal end and a distal end and comprises inner and outer coaxial tubes. The outer coaxial tube is called an outer catheter, or sheath, 11, 21. The inner coaxial tube is called a shaft 13, 23.

[0032] Shaft 13, 23 has a proximal end 13a, 23a, a distal end 13b, 23b and a stent retaining area 15, 25. Optionally, shaft 13, 23 may include a pusher band 17, 27 attached to the stent retaining area 15, 25, a distal tip 18, 28 attached to the shaft distal end 13b, 23b and a wire guide lumen 19, 29. Shaft 13, 23 can be made from any suitable material known in the art including, but not limited to, polyethylene ether ketone (PEEK), polytetrafluoroethylene (PTFE), polyamide, polyurethane, polyethylene and nylon, including multi-layer or single layer structures and may also include reinforcement wires, braid wires, coils and or filaments. Preferably, shaft 13, 23 comprises a proximal portion made of a relatively rigid material such as stainless steel or any other suitable material known in the art.

[0033] Stent retaining area 15, 25 is preferably located on a distal portion of the shaft 13, 23. The stent retaining area 15, 25 retains a stent 16, 26 to be deployed in the bifurcation. Preferably, stent 16, 26 is a self-expanding stent.

[0034] Pusher band 17, 27 helps to prevent the stent from proximally migrating as the outer catheter 11, 21 is withdrawn proximally to deploy the stent. The pusher band 17, 27 is located proximal to the stent 16, 26 such that the proximal end of the stent 16, 26 abuts the pusher band 17, 27 as shown in Figures 5-10A and 12.

[0035] Distal tip 18, 28 helps prevent fluids from entering the outer catheter 11, 22 as the introducer 10, 20 is navigated through the body lumens. As shown in Figures 5-10A and 12, distal tip 18, 28 has a proximal end 18a, 28a and a distal end 18b, 28b. The distal tip proximal end 18a, 28a has a diameter that is less than the diameter of the distal outer catheter distal end 14b, 24b and is received therein. Preferably, the distal tip 18, 28 tapers to a smaller diameter towards its distal end 18b, 28b as shown in Figures 7, 7A and 12. Distal tip 18, 28 can be made from

40 positioned at any location along the length of the introducer 10, 20 is contemplated. In addition, the wire guide lumen 19, 29 may also comprise a channel or split.

[0040] Aperture 30, 40 provides the stent delivery system of the present invention with rapid-exchange capabilities. In particular, by extending the wire guide 32, 42 through only a distal portion of the wire guide lumen 19, 29, the delivery system can be removed from a wire guide 32, 42 having a length substantially shorter than the length necessary if the wire guide 32, 42 were extended through the entire length of the wire guide lumen 19, 29.

[0041] Referring to Figure 5, outer catheter, or sheath, 11, 21 has a proximal end 11a, 21a and a distal end 11b, 21b. The outer catheter, or sheath, 11, 21 further comprises a proximal outer catheter 12, 22 having proximal and distal ends, 12a, 22a and 12b, 22b respectively, and a distal outer catheter 14, 24 having proximal and distal ends, 14a, 24a and 14b, 24b respectively. The distal end 12b, 22b of the proximal outer catheter 12, 22 is attached to the proximal end 14a, 24a of the distal outer catheter 14, 24 to form outer catheter 11, 22.

[0042] In one embodiment, the proximal outer catheter 12, 22 and the distal outer catheter 14, 24 comprise separate catheters, or sheaths as shown in Figures 5-10A and 12. The distal end 12b, 22b of proximal outer catheter 12, 22 can be attached to the proximal end 14a, 24a of distal outer catheter 14, 24 by any method known in the art including, but not limited to, heat fusing, adhesive bonding, chemical bonding or mechanical fitting. In an alternate embodiment (not shown), the proximal outer catheter 12, 22 and the distal outer catheter 14, 24 comprise portions of a single catheter or sheath.

[0043] Proximal outer catheter 12, 22 further comprises a proximal outer diameter and the distal outer catheter 14, 24 further comprises a distal outer diameter. In one embodiment the sum of the first outer catheter diameter and the second outer catheter diameter is less than the inner diameter of the working channel 8a of the endoscope 8.

[0044] Referring to the embodiment shown in Figure 12, a pair of introducers 10, 20 are disposed next to each other in the working channel 8A of an

Thus, introducers 10, 20 having distal outer catheter diameters less than about 6 French used to place stents having compressed configurations less than about 0.069 inches that may become available in the future are contemplated as being within the scope of the claims of the invention.

[0047] Returning to Figure 5, introducer 10, 20 may further comprise a handle 33, 43 attached to proximal outer catheter 12, 22 proximal end 12a, 22a. Handle 33, 43 may optionally comprise a gripping member 34, 44 a connector 35, 45 having an injection port 36, 46 and/or a releasable locking mechanism 37, 47. Injection port 36, 46 is used to irrigate the shaft 13, 23 and stent 16, 26 with sterile water prior to use. Releaseable locking mechanism 37, 47 releasably affixes shaft 13, 23 to outer catheter 11, 21.

[0048] Preferably, proximal outer catheter 12, 22 further comprises a support portion 12d, 22d adjacent to the handle 33, 43 as shown in Figure 5. Preferably, the support portion 12d, 22d of the proximal outer catheter 12, 22 is not positioned within the working channel 8a of the endoscope 8. Support portion provides additional column strength to the introducers 10, 20 as the introducers 10, 20 are manipulated through the lumens of a patient. Support portion 12d, 22d may comprise a separate support catheter having an outer diameter of about 7 to about 9 French. Preferably, the outer diameter of support portion 12d, 22d is about 7 French.

[0049] Outer catheter, or sheath, 11, 21 can be made from any suitable material known in the art including, but not limited to, PTFE, polyamide, polyurethane, polyethylene and nylon including multi-layer or single layer structures and may also include reinforcement wires, braid wires, coils and or filaments. Preferably, at least the distal portion of outer catheter 11, 21 is made of any relatively clear material so that the stent 16, 26 mounted on the stent retaining area 15, 25 of the shaft 13, 23 can be viewed.

[0050] The stent delivery system 1 of the present invention is used to place first and second stents 16, 26 into a bifurcation having strictures 3 in the main lumen 2a and the first and second branch lumens 2b, 2c as follows. A distal end of a first wire guide 32 is advanced through the main lumen and into the first

CLAIMS

1. A stent delivery system comprising:
 - a) a first introducer having proximal and distal ends comprising:
 - i) a first outer catheter having proximal and distal ends, the first outer catheter comprising:
 - A) a first proximal outer catheter having proximal and distal ends and a first proximal outer diameter; and
 - B) a first distal outer catheter having proximal and distal ends and a first distal outer diameter;wherein the first proximal outer catheter distal end is connected to the first distal outer catheter proximal end;
wherein the first proximal outer diameter is less than the first distal outer diameter;
 - ii) a first inner shaft located coaxially within said first outer catheter, the first inner shaft having proximal and distal ends, a first stent retaining area located on a distal portion of the first inner shaft; and
 - b) a second introducer having proximal and distal ends comprising:
 - i) a second outer catheter having proximal and distal ends, the second outer catheter comprising:
 - A) a second proximal catheter having proximal and distal ends and second proximal outer diameter; and
 - B) a second distal catheter having proximal and distal ends and a second distal outer diameter;

8. The stent delivery system of claim 5, wherein the first wire guide lumen extends proximally from the first introducer distal end for a distance of up to about 20 cm.

9. The stent delivery system of claim 5, wherein the first wire guide lumen extends proximally from the first introducer distal end for a distance of up to about 1 cm.

10. The stent delivery system of claim 1, wherein the first introducer further comprises a first stent tip attached to the distal end of the first inner shaft.

11. The stent delivery system of claim 10, wherein the first stent tip is tapered.

12. The stent delivery system of claim 1, wherein the first proximal outer catheter and the first distal outer catheter comprise two separate catheters.

13. The stent delivery system of claim 1, wherein the sum of the first proximal outer diameter and the second distal outer diameter is less than the inner diameter of the working channel of the endoscope.

14. The stent delivery system of claim 1 wherein the sum of the first proximal outer diameter and the second distal outer diameter and at least one of a first and second wire guide diameters is less than the inner diameter of the working channel of the endoscope.

15. The stent delivery system of claim 1, wherein the first proximal outer catheter is disposed adjacent to the second distal outer catheter while inside the working channel of the endoscope.

16. The stent delivery system of claim 1, wherein the first proximal outer diameter is disposed adjacent to the second distal outer diameter while inside the working channel of the endoscope.

iv) a first stent having proximal and distal ends mounted on the first stent retaining area of the inner shaft such that the first stent proximal end abuts the first pusher band;

v) a first wire guide lumen extending proximally from the first introducer distal end through at least a portion of the first introducer;

b) a second introducer comprising:

i) an second outer catheter having proximal and distal ends, the second outer catheter comprising:

A) a second proximal outer catheter having proximal and distal ends and second proximal outer diameter; and

B) a second distal outer catheter having proximal and distal ends and a second distal outer diameter;

wherein the second proximal outer diameter is less than the second distal outer diameter; and

wherein the second proximal outer catheter distal end is connected to the second distal outer catheter proximal end;

ii) a second inner shaft located coaxially within said second outer catheter, the second shaft having proximal and distal ends, a second stent retaining area located on a distal portion of the second inner shaft, a second pusher band located proximate the second stent retaining area; and

iii) a second stent tip attached to the distal end of the second inner shaft;

iv) a second stent having proximal and distal ends mounted on the second stent retaining area of the second inner shaft such that the second stent proximal end abuts the second pusher band;

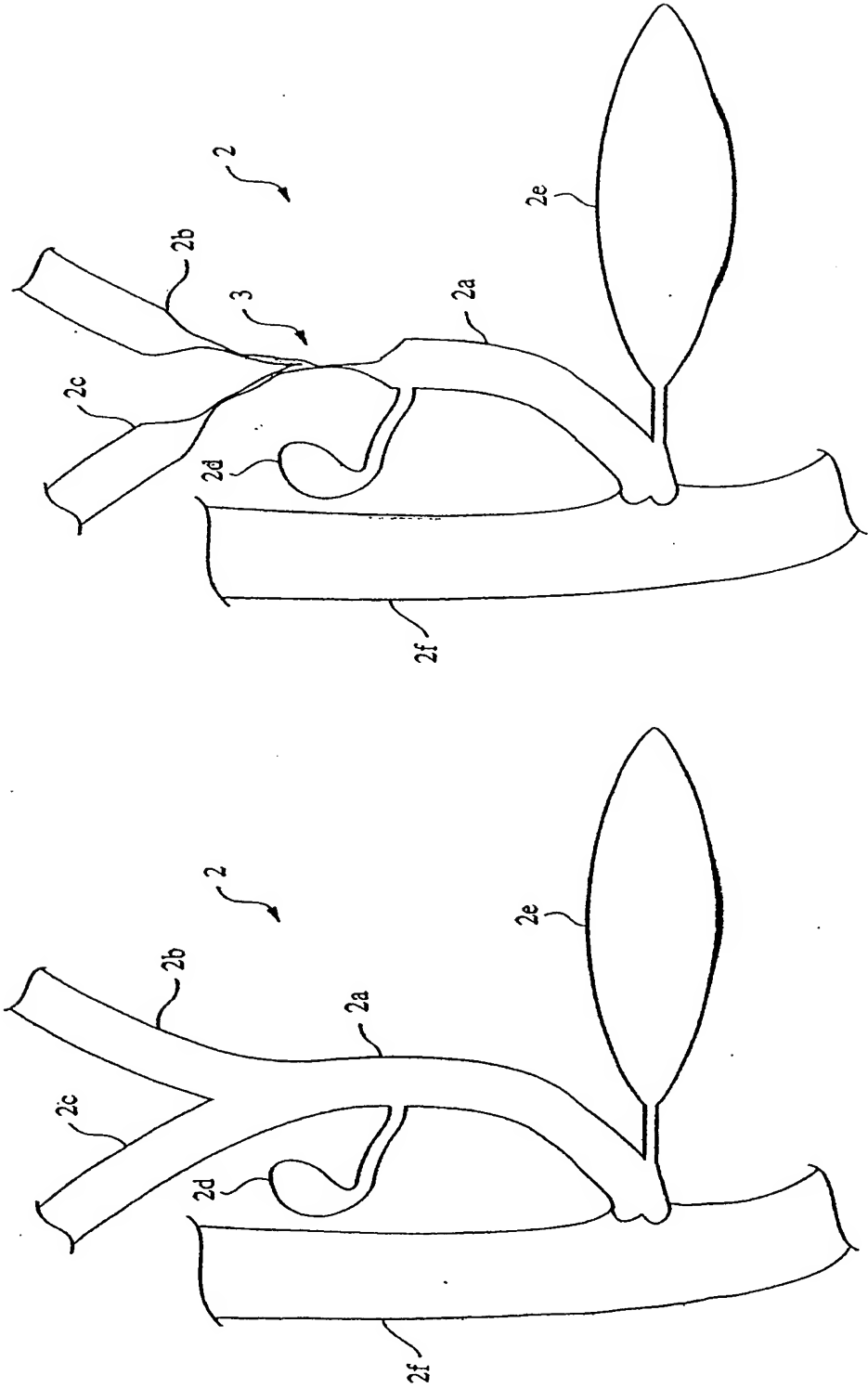


FIG. 2

FIG. 1

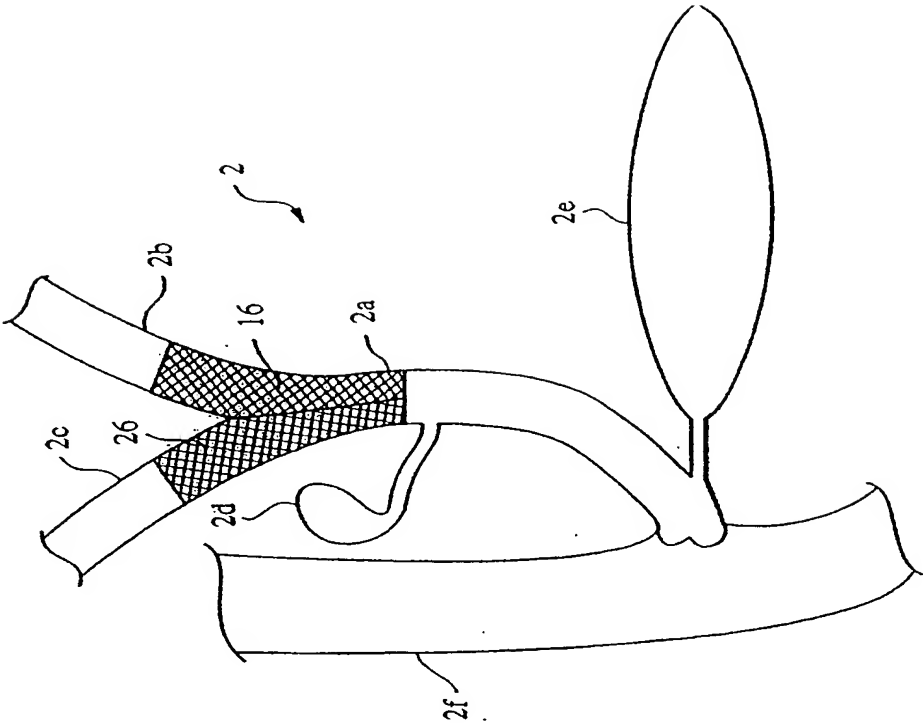


FIG. 4

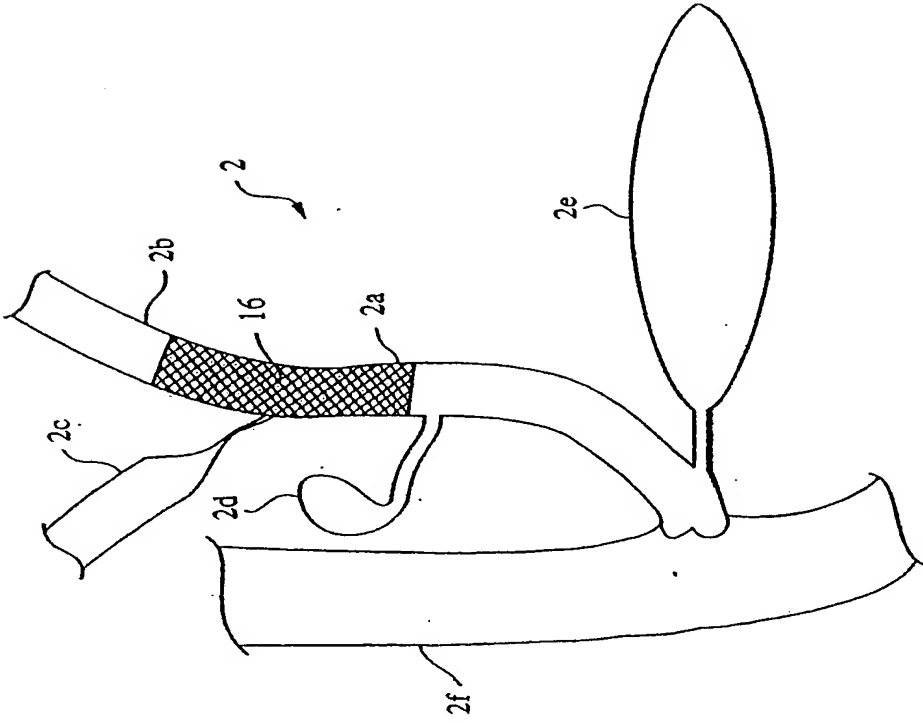


FIG. 3
PRIOR ART

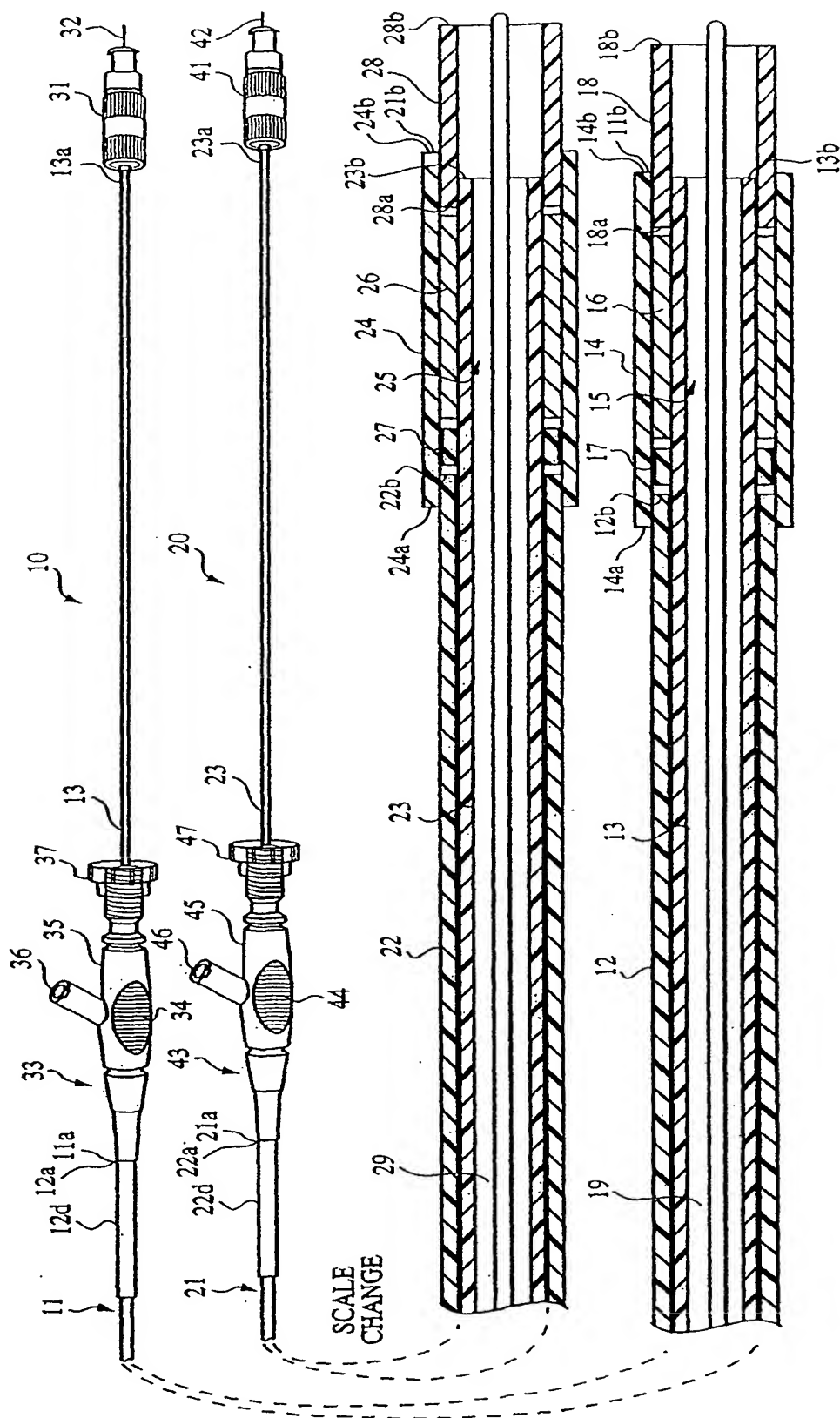


FIG. 5

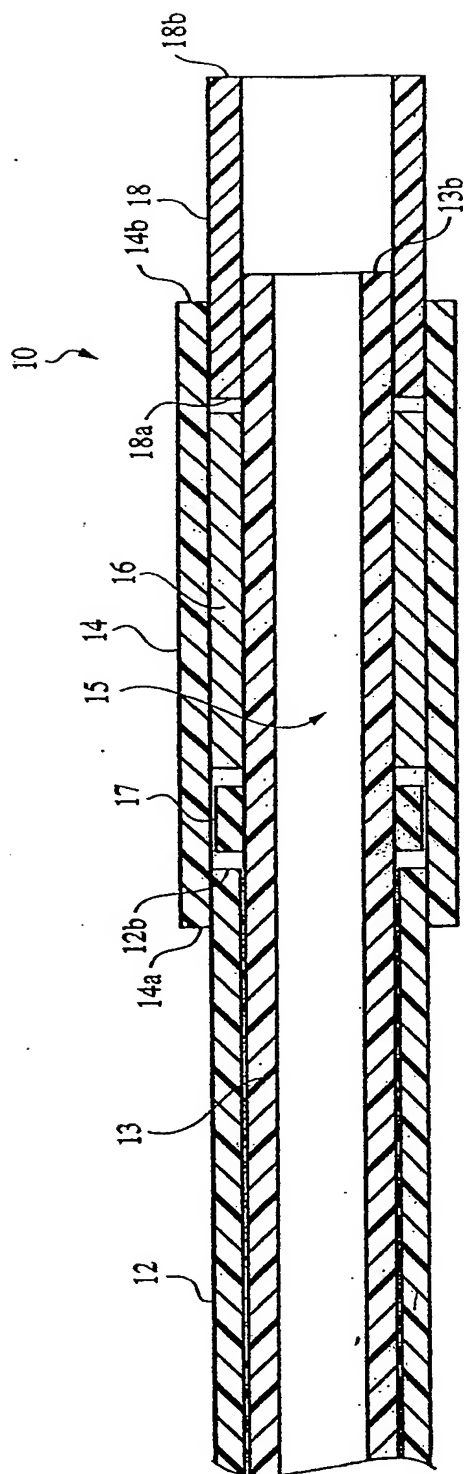


FIG. 6

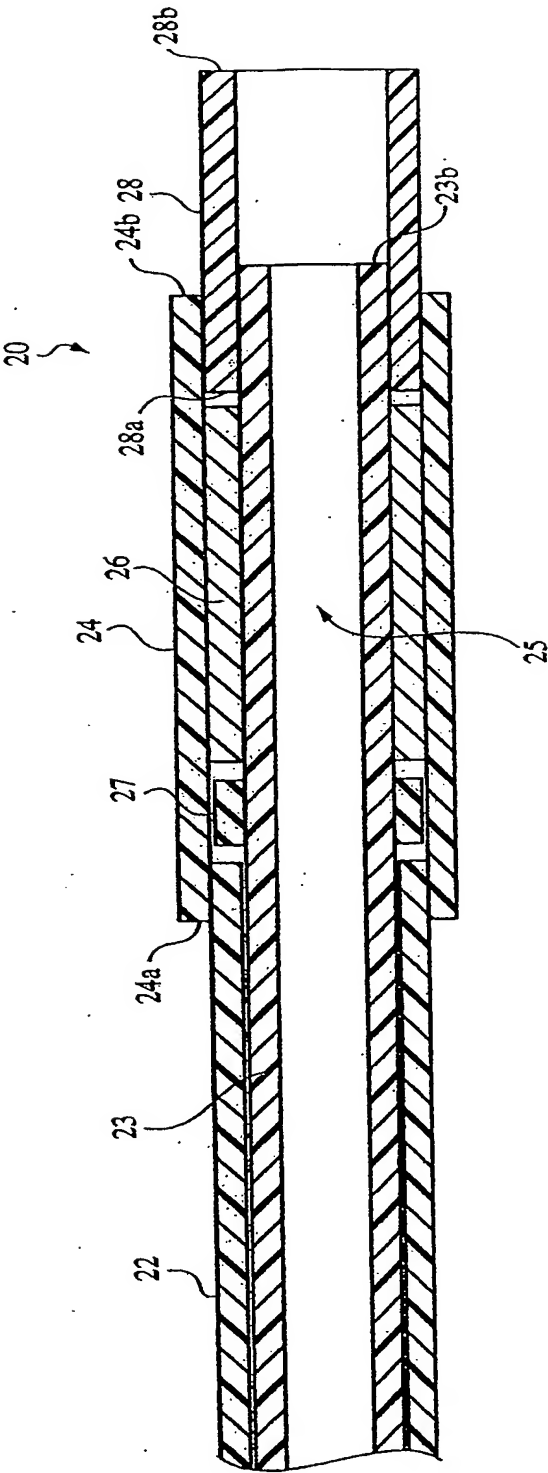


FIG. 6A

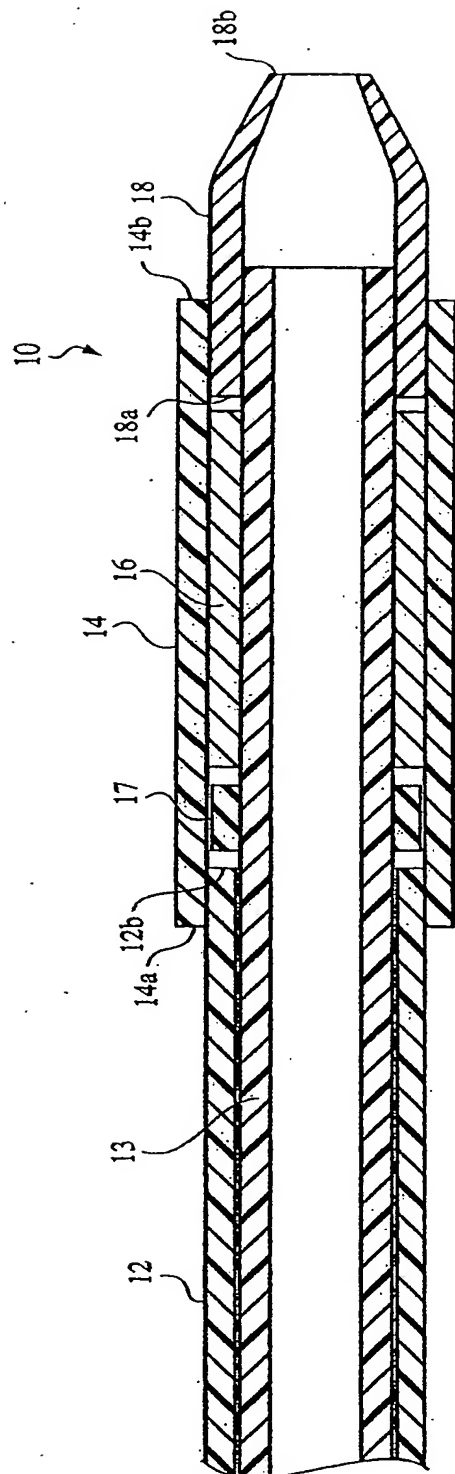


FIG. 7

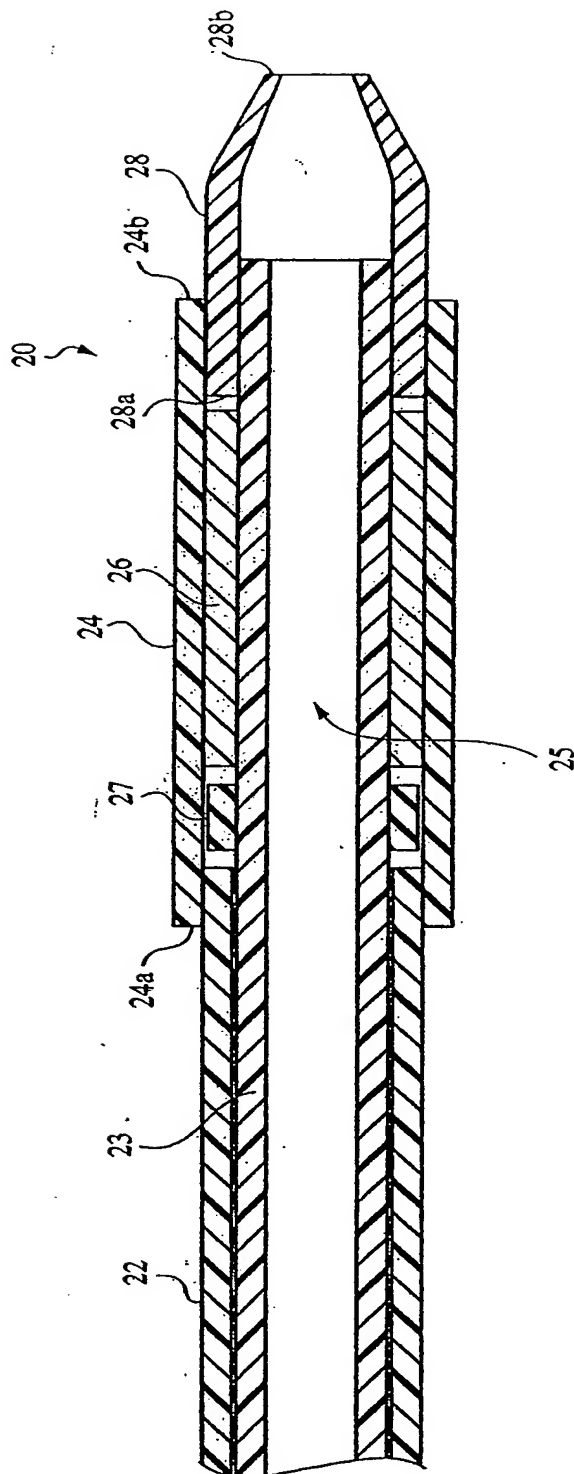


FIG. 7A

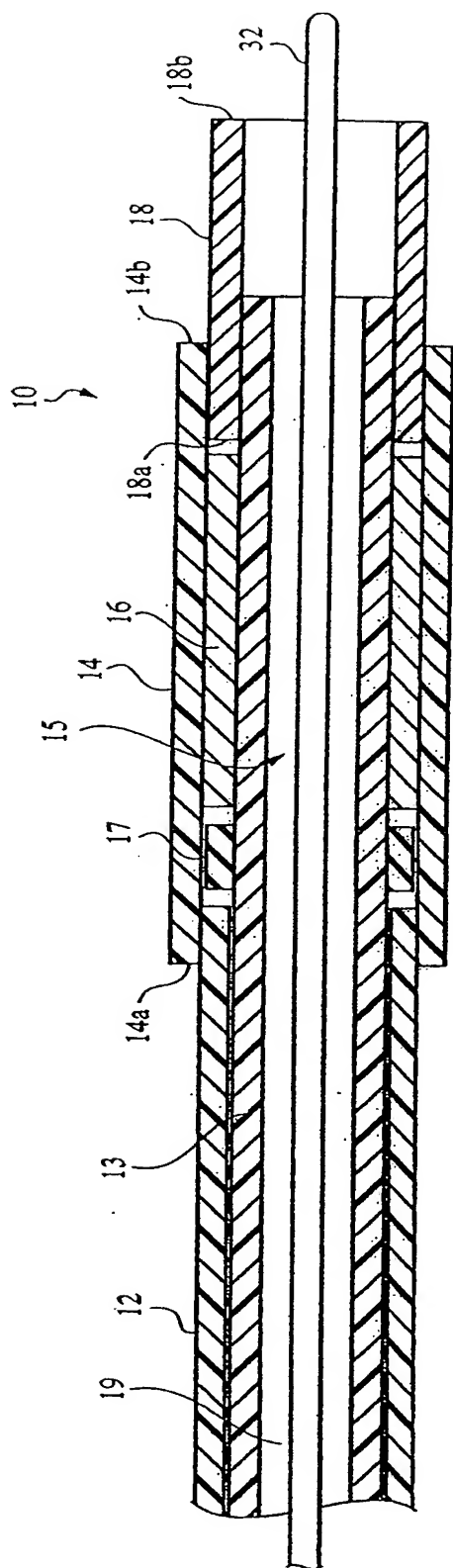


FIG. 8

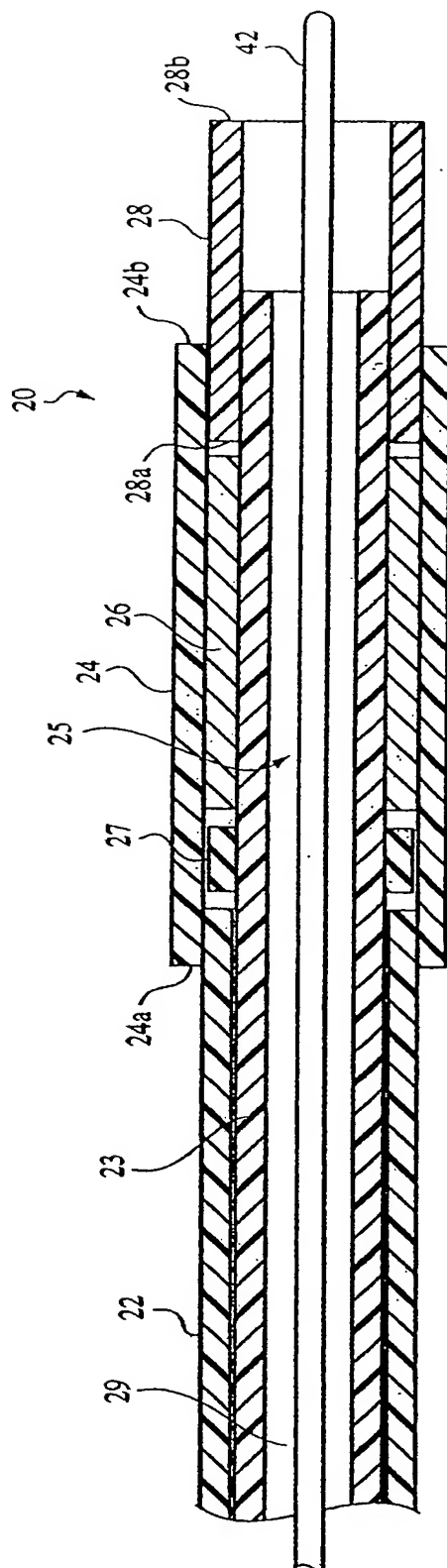


FIG. 8A

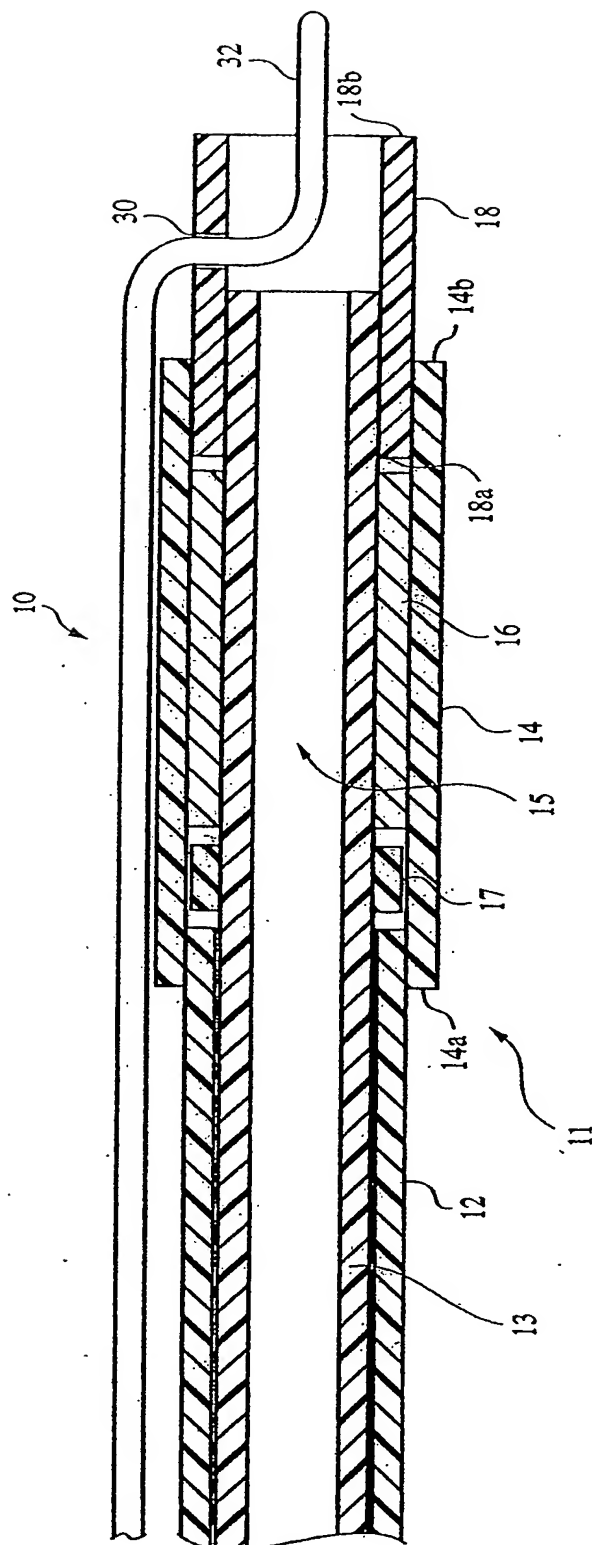


FIG. 9

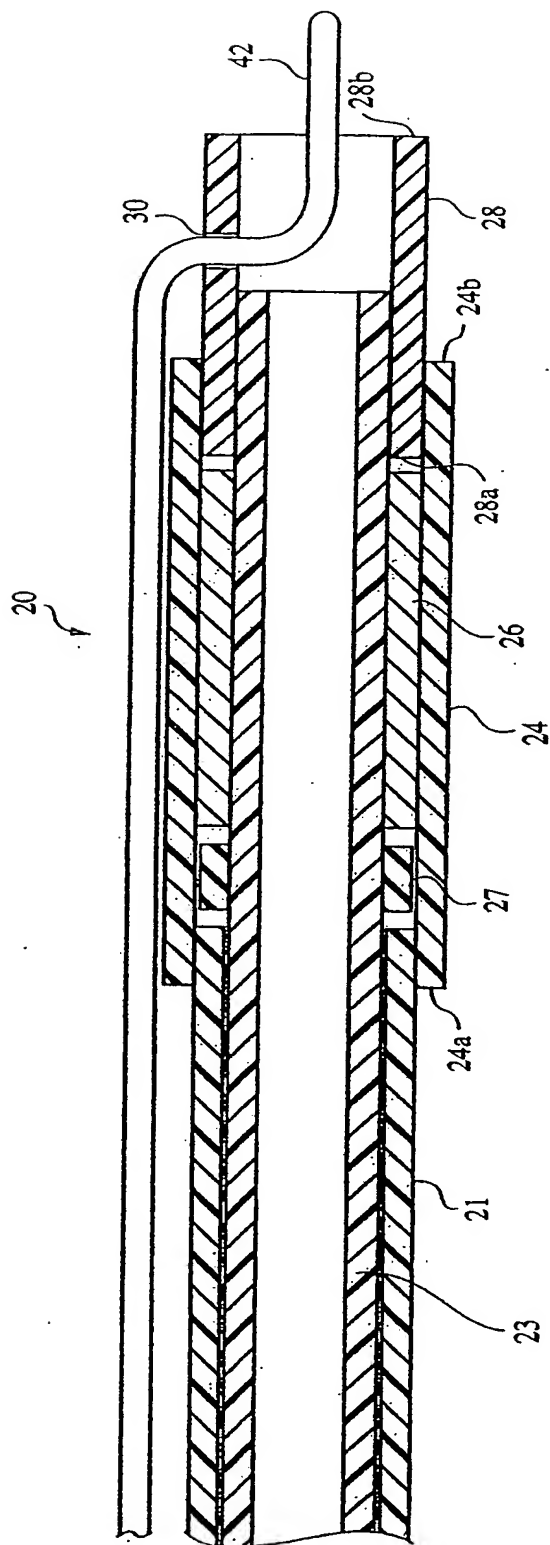


FIG. 9A

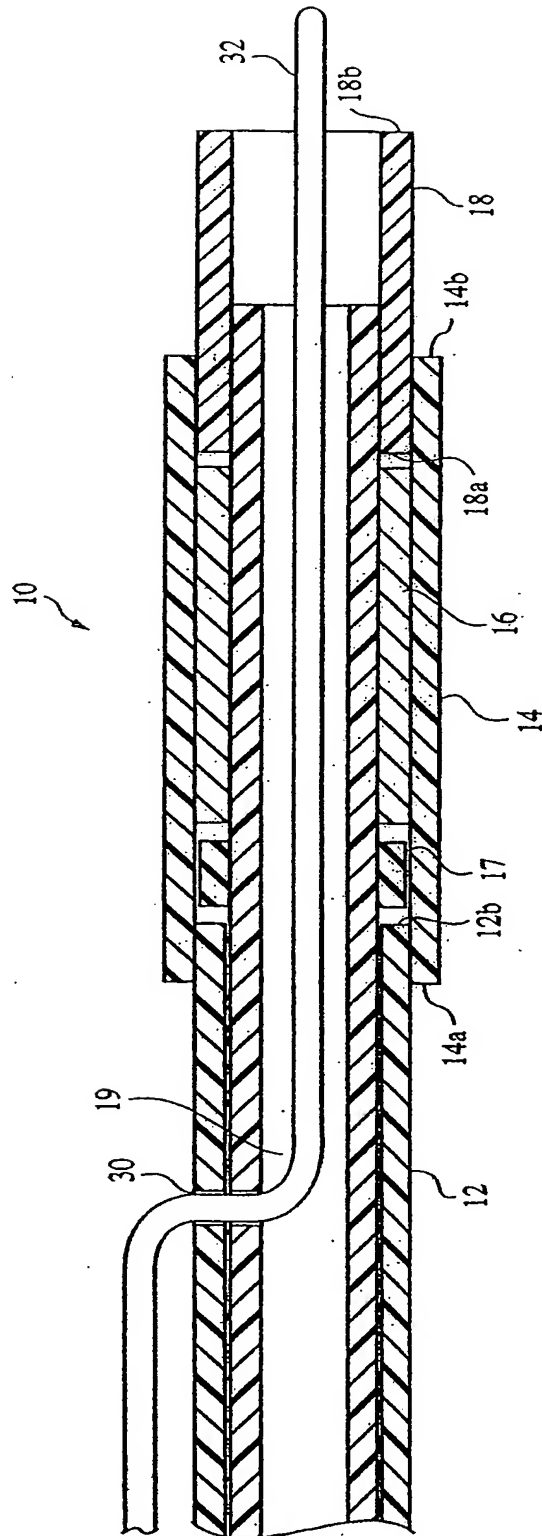


FIG. 10

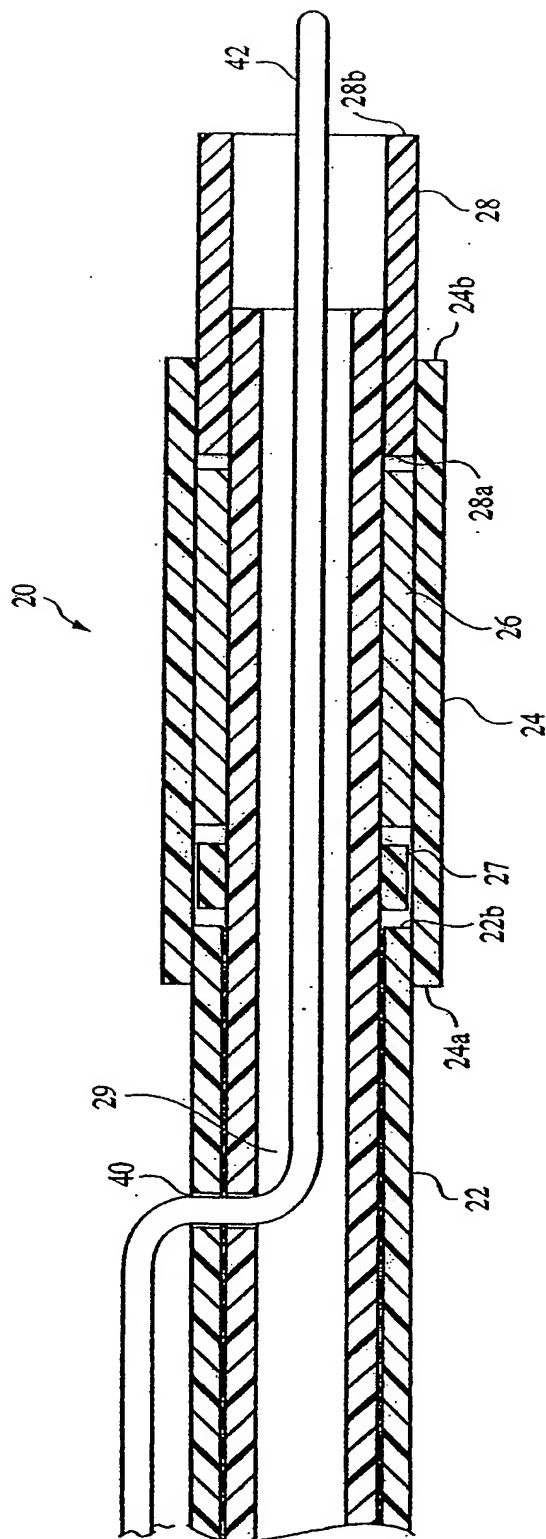


FIG. 10A

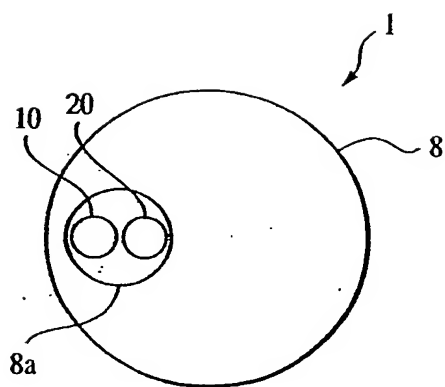


FIG. 11

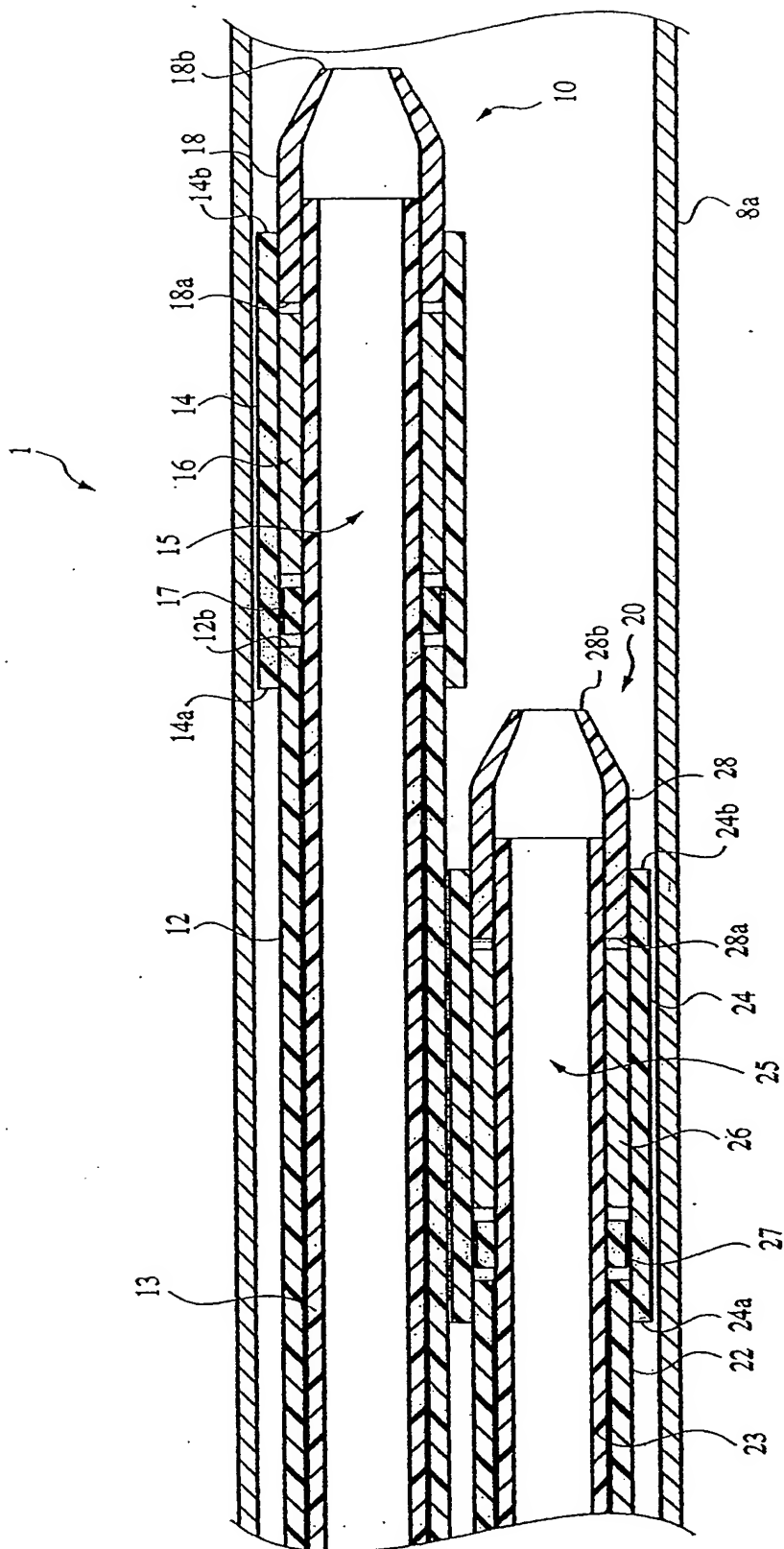


FIG. 12

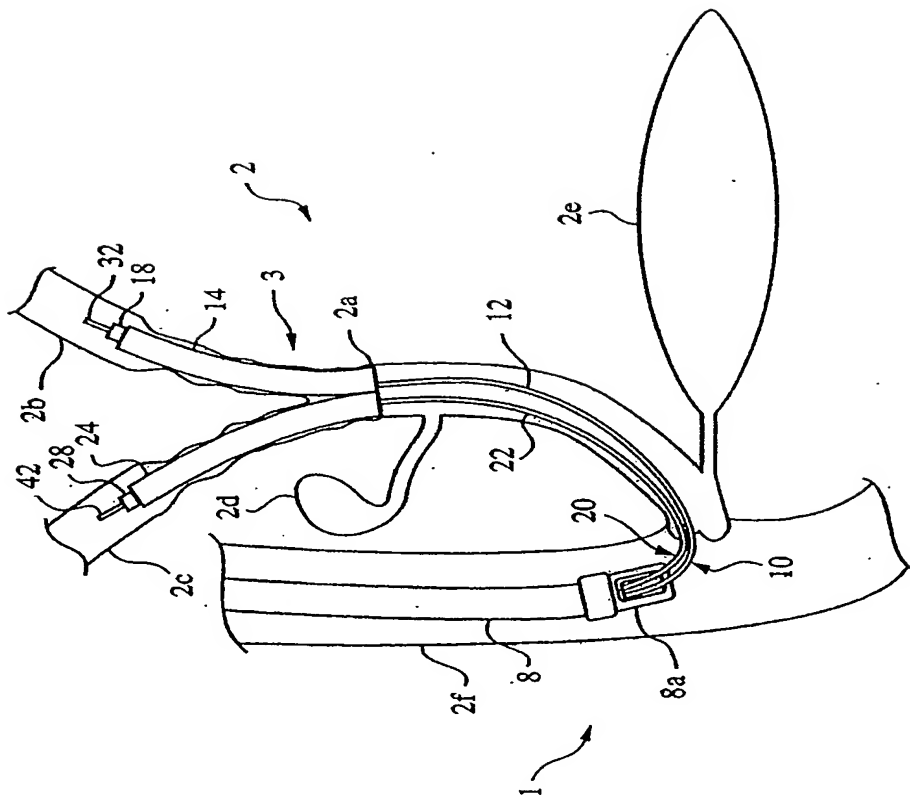


FIG. 13

INTERNATIONAL SEARCH REPORT

Inter al Application No
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A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2002/161341 A1 (STINSON JONATHAN S ET AL) 31 October 2002 (2002-10-31) figures 5,11a paragraph '0067!	1-23
Y	US 2003/149444 A1 (KHAW KENNETH) 7 August 2003 (2003-08-07) figures 1,2 paragraphs '0035!, '0036! paragraph '0060!	1-23
Y	US 5 571 135 A (FRASER ET AL) 5 November 1996 (1996-11-05) figure 8	1,20
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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4 April 2005

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14/04/2005

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2002161341	A1	31-10-2002	WO 02087469 A2 US 2004098105 A1	07-11-2002 20-05-2004
US 2003149444	A1	07-08-2003	AU 2003212943 A1 WO 03065935 A1 US 2005004645 A1	02-09-2003 14-08-2003 06-01-2005
US 5571135	A	05-11-1996	AT 288298 T CA 2174750 A1 DE 69434259 D1 EP 0746375 A1 JP 3566963 B2 JP 9503945 T WO 9511055 A1 US 5445646 A US 6530947 B1 US 2003212447 A1 US 6562063 B1 US 5989280 A	15-02-2005 27-04-1995 10-03-2005 11-12-1996 15-09-2004 22-04-1997 27-04-1995 29-08-1995 11-03-2003 13-11-2003 13-05-2003 23-11-1999
WO 9635470	A	14-11-1996	US 5599300 A AU 5857696 A BR 9608135 A CA 2220683 A1 JP 11505141 T WO 9635470 A1 US 5843091 A	04-02-1997 29-11-1996 07-12-1999 14-11-1996 18-05-1999 14-11-1996 01-12-1998
WO 0230329	A	18-04-2002	AU 9671601 A CA 2424042 A1 WO 0230329 A2 US 2002052648 A1 US 2002072790 A1	22-04-2002 18-04-2002 18-04-2002 02-05-2002 13-06-2002
US 4994066	A	19-02-1991	NONE	